

## **REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

### **I. CLAIM STATUS AND AMENDMENT**

Claims 39-40, 42, 48, and 50 are pending in this application.

Claims 1-38, 41, 43-47, and 49 stand cancelled without prejudice or disclaimer thereto.

Claims 39-40, 42, 48, and 50 have been examined on the merits and stand rejected.

Claim 39 is amended herein to clarify the claimed invention. Support for this amendment may be found, inter alia, in the claims as originally filed and in the specification, e.g. “coated complex particles having an average particle diameter of 200 nm or less” is based on the paragraph [0145] in the published specification; “lead particles having an average particle diameter of 50 to 150 nm” is based on the paragraph [0129] in the published specification; and “the ratio of the lead particles : the total amount of the plasmids and the anionic polymer is 2:1 to 200 : 1 by weight” is based on the paragraph [0126] in the published specification.

Claim 50 is cancelled herein without prejudice or disclaimer thereto.

No new matter has been added.

### **II. REJECTION UNDER 35 USC 103(a)**

Claims 39-40, 42, 48, and 50 remain rejected under 35 USC 103(a) as being unpatentable over Kato et al. (US 2004/0022938).

Applicants respectfully traverse this rejection as applied to the amended claims.

It is noted that claim 39 is amended herein to recite:

**39. (Currently Amended)** A method of producing coated complex particles having an average particle diameter of 200 nm or less, comprising the steps of:

~~dispersing or dissolving one or more substance(s) selected from plasmids and siRNA and an anionic polymer in a liquid with lead particles having an average particle diameter of 50 to 150 nm, wherein the lead particles comprise a lipid assembly, a liposome, an emulsion particle or a polymeric micelle, containing~~

(i) one or more substance(s) selected from polyethylene glycolated lipids, polyethylene glycol sorbitan fatty acid esters, polyethylene glycol fatty acid esters, polyglycerolated lipids, polyglycerol fatty acid esters, polyoxyethylene polypropylene glycol, glycerol fatty acid esters and polyethylene glycol alkyl ethers, and

(ii) a cationic substance;

dispersing or dissolving plasmids in the liquid with the lead particles, whereby complex particles wherein the substance(s) selected from plasmids and siRNA and the anionic polymer adhere to the lead particles to obtain complex particles are obtained;

preparing a liquid (liquid A) containing a polar organic solvent in which obtained complex particles are dispersed and a lipid membrane component is dissolved; and

coating the complex particles with a lipid membrane composed of the lipid membrane component by reducing the ratio of the polar organic solvent in the liquid A.

which is characterized in dispersing or dissolving an anionic polymer in the liquid with the lead particles when the plasmids disperse or dissolve in the liquid with the lead particles, whereby the complex particles wherein the plasmids and the anionic polymer adhere to the lead particles are obtained,

wherein the ratio of the lead particles : the total amount of the plasmids and the anionic polymer is 2:1 to 200 : 1 by weight.

Applicants respectfully assert that a person having ordinary skill in the art would find no reason in the teachings of the cited reference to modify its teachings in order to arrive at the claimed invention, as amended herein, nor would he have any reasonable expectation of success in doing so.

Therefore, Applicants respectfully assert that the rejection is untenable as applied to the amended claims and should be withdrawn.

### **III. AMENDMENT TO THE SPECIFICATION**

It is noted that the specification is amended herein, based on the PCT specification, to correct minor translation errors made without deceptive intent. No new matter has been added.

**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully asserted that the present application is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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